

Message

From: Vandenberg, John [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCAE2B98A04540FB8D099F9D4DEAD690-VANDENBERG, JOHN]
Sent: 4/29/2011 6:07:27 PM
To: Cogliano, Vincent [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51f2736376ac4d32bad2fe7cfef2886b-Cogliano, Vincent]
Subject: Fw: 3 Parts re Methanol Letter 1) draft response to Maria Hegsted, 2) my call with George Cruzan, and 3) J Gift evaluation re Methanol Institute Letter
Attachments: McCallum2011.pdf; Sweeting2010.pdf

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----- Forwarded by John Vandenberg/RTP/USEPA/US on 04/29/2011 02:08 PM -----

From: Jeff Gift/RTP/USEPA/US
To: John Vandenberg/RTP/USEPA/US@EPA
Cc: Debra Walsh/RTP/USEPA/US@EPA, Reeder Sams/RTP/USEPA/US@EPA, Stan Barone/RTP/USEPA/US@EPA, Jeff Gift/RTP/USEPA/US@EPA, JMichael Davis/RTP/USEPA/US@EPA, John Rogers/RTP/USEPA/US@EPA, Reeder Sams/RTP/USEPA/US@EPA, Paul Schlosser/RTP/USEPA/US@EPA, Allen Davis/RTP/USEPA/US@EPA
Date: 04/29/2011 12:31 PM
Subject: Re: Fw: 3 Parts re Methanol Letter 1) draft response to Maria Hegsted, 2) my call with George Cruzan, and 3) J Gift evaluation re Methanol Institute Letter

John et al.,

These are the only papers out of that U. of Toronto lab that I am aware of. Note that the 2011 paper deals with mutagenicity of methanol, not developmental toxicity and the 2010 paper basically concluded that rabbits might be a more useful model than rodents for assessing the developmental toxicity of methanol. Neither paper seems critical to the assessment, but both should and will be assessed at peer review.



McCallum2011.pdf



Sweeting2010.pdf

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From: John Vandenberg/RTP/USEPA/US
To: Jeff Gift/RTP/USEPA/US@EPA, Reeder Sams/RTP/USEPA/US@EPA, Debra Walsh/RTP/USEPA/US@EPA
Date: 04/29/2011 12:07 PM
Subject: Fw: 3 Parts re Methanol Letter 1) draft response to Maria Hegsted, 2) my call with George Cruzan, and 3) J Gift evaluation re Methanol Institute Letter

FYI and Jeff, please note Lynn's comment. Any thoughts on this?

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----- Forwarded by John Vandenberg/RTP/USEPA/US on 04/29/2011 12:08 PM -----

From: Lynn Flowers/DC/USEPA/US
To: John Vandenberg/RTP/USEPA/US@EPA
Cc: Audrey Hoffer/DC/USEPA/US@EPA, Becki Clark/DC/USEPA/US@EPA, Darrell Winner/DC/USEPA/US@EPA
Date: 04/29/2011 11:52 AM
Subject: Re: 3 Parts re Methanol Letter 1) draft response to Maria Hegsted, 2) my call with George Cruzan, and 3) J Gift evaluation re Methanol Institute Letter

John: Quick work!

Deliberative Process / Ex. 5

Lynn

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From: John Vandenberg/RTP/USEPA/US
To: Becki Clark/DC/USEPA/US@EPA, Darrell Winner/DC/USEPA/US@EPA, Lynn Flowers/DC/USEPA/US@EPA, Audrey Hoffer/DC/USEPA/US@EPA
Date: 04/29/2011 11:45 AM
Subject: 3 Parts re Methanol Letter 1) draft response to Maria Hegsted, 2) my call with George Cruzan, and 3) J Gift evaluation re Methanol Institute Letter

I put relevant information together in one email to make it easier to see the parts. Please let me know if any questions, and also need feedback re Part 1.

Part 1)

Audrey sent me this late yesterday. My draft response in Blue. **Let me know of edits, deadline is 10 am Monday**

From: Mollie Lemon/DC/USEPA/US
To: Carolyn Hubbard/DC/USEPA/US@EPA
Cc: Megan Maguire/DC/USEPA/US@EPA
Date: 04/28/2011 03:55 PM
Subject: ACTION: Inside EPA q's on non-cancer IRIS assessment on methanol (deadline: 10 am 5/2)

Hi all--a few questions from Maria Hegsted at Inside EPA. Can we try to respond? Thanks!!

I've a few questions regarding the draft non-cancer IRIS assessment methanol that was released last week.

1. The non-cancer assessment appears similar, if not the same, as the non-cancer section of the January 2010 draft IRIS assessment. Were substantive changes made between the two versions? Response: The 2011 draft IRIS non-cancer assessment for methanol contains the same information, analyses and conclusions related to non-cancer outcomes as was included in the 2010 draft IRIS assessment for methanol. The following information was provided in the Federal Register notice at the time of public release of the 2010 draft (bold emphasis added):

In January 2010, EPA released an external peer review draft IRIS Toxicological Review for methanol (EPA/635/R-09/013), containing both cancer and non-cancer analyses, and requested that the Science Advisory Board conduct a review of this human health assessment. Following a report from the National Toxicology Program, EPA placed the external peer review of the draft IRIS Methanol Toxicological Review on hold. The National Toxicology Program report recommended that pathology reviews be carried out to resolve differences of opinion in the diagnoses of certain tumors reported in a Ramazzini Institute methanol research study, which was cited and used to support some of the conclusions in the draft IRIS assessment. As a result, EPA and the National Institute of Environmental Health Sciences plan to jointly sponsor an independent Pathology Working Group (PWG) review of select studies conducted at the Institute. EPA is today releasing the draft IRIS Methanol Toxicological Review (Non-Cancer) for public comment while continuing to hold the cancer assessment that was previously released in January 2010. The data and studies used in the draft IRIS Methanol Toxicological Review (Non-Cancer) are unrelated to the tumor diagnoses being re-examined by the PWG. **The information, analyses and conclusions of the draft assessment announced in this notice are identical to the non-cancer portions of the draft assessment previously released in January 2010.** Comments relevant to the non-cancer methanol assessment that were received during the previous public comment period for the joint cancer and non-cancer assessment will be considered along with new comments.

2. Was a search conducted for new literature prior to releasing the new non-cancer methanol document? What was the criteria for adding new studies (if any) to the assessment? Response: EPA is continually identifying new literature related to the health assessment of methanol; as noted in response to Question 1, the information, analyses and conclusions of the 2011 draft are identical to the non-cancer portions of the draft previously released in January 2010 hence no new studies were added.

3. Did EPA review the methanol-industry funded research performed at the University of Toronto (Sweeting et al and McCallum et al, both 2010) before releasing the new methanol document? Why isn't it referenced in the draft document? See response to questions 1 and 2.

Part 2:

As I noted in my message from 4/19, I spoke with George Cruzan when he called last Tuesday and it seems he worked with Greg Dolan to cherry picked/twisted my comments.

At the listening session I'll politely share my displeasure with George about this.

my summary from 4/19:

All -

Deliberative Process / Ex. 5

John

Part 3:

Email from Jeff Gift to Methanol team providing his take on MI comments;

From: Jeff Gift/RTP/USEPA/US
To: Stan Barone/RTP/USEPA/US@EPA, Jeff Gift/RTP/USEPA/US@EPA, JMichael Davis/RTP/USEPA/US@EPA, John Rogers/RTP/USEPA/US@EPA, Reeder Sams/RTP/USEPA/US@EPA, Paul Schlosser/RTP/USEPA/US@EPA, Allen Davis/RTP/USEPA/US@EPA
Cc: John Vandenberg/RTP/USEPA/US@EPA, Debra Walsh/RTP/USEPA/US@EPA
Date: 04/29/2011 10:28 AM
Subject: Fw: Methanol Institute Letter on Methanol Noncancer Assessment

Methanol Team,

FYI, MI has submitted the attached letter to Paul Anastas regarding the methanol noncancer assessment. Briefly, MI gives 4 basic reasons that they feel the methanol peer review should be halted: (1) the RfC/D ignore background levels of methanol from endogenous dietary sources, (2) there is new literature that proposes that ROS plays a role in the developmental effects observed in rodents exposed to methanol and humans produce less ROS from methanol exposure than rodents, (3) EPA should have first responded to existing MI and DOD comments and (4) the new process will not allow them enough time to verbally present their issues to the peer review panel.

Deliberative Process / Ex. 5

I will try to keep you informed on what develops as a result of this.

Regards,

Jeff

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----- Forwarded by Jeff Gift/RTP/USEPA/US on 04/29/2011 09:24 AM -----

From: Greg Dolan <gdolan@methanol.org>
To: Paul Anastas/DC/USEPA/US@EPA
Cc: Kevin Teichman/DC/USEPA/US@EPA, Jeff Gift/RTP/USEPA/US@EPA, Becki Clark/DC/USEPA/US@EPA, Desk IRIS@EPA, Bernard King/DC/USEPA/US@EPA, Vincent Cogliano/DC/USEPA/US@EPA
Date: 04/28/2011 04:48 PM
Subject: Methanol Institute Letter on Methanol Noncancer Assessment

Dear Dr. Anastas:

Attached is a letter from the Methanol Institute requesting that you withdraw the noncancer IRIS assessment of methanol from its current public and peer review cycle. In our view, the current assessment is so fundamentally flawed that to proceed with peer review of the document would be meaningless, and in fact, counterproductive to good scientific process. We realize that your office often receives requests to delay or re-do your IRIS assessments, so the attached letter explains why we believe that developments since the initial draft was released in December 2009 fundamentally undermine the core elements of the current assessment and therefore necessitate a re-working NOW of the assessment rather than later after peer review.

We would like to meet with you to discuss this request in more detail, and will call your office in a few days to seek a mutually satisfactory time for such a meeting.

Gregory Dolan
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[attachment "MI Letter to Dr Anastas on Methanol Noncancer Assessment.pdf" deleted by Jeff Gift/RTP/USEPA/US]